REMARKS

Claims 1-7 are canceled. Claims 1-5 were canceled previously. Claims 6 and 7 are canceled with the present amendment. New claims 10 and 11 have been added. Claims 8 and 9 were amended to depend on new claims 10 and 11 instead of canceled claims 6 and 7.

Support for new claims 10 and 11 can be found on page 18 for the general construction of the backing layer. Support for the acrylic pressure-sensitive adhesive layer in new claim 10 can be found on page 7, lines 15-20 and original claim 3. Support for the acrylic pressure-sensitive adhesive layer in new claim 11 can be found on page 8, lines 3-8 and original claim 4.

To summarize the currently pending claims and disclosure, the backing layer is a two-ply laminated structure comprising:

(1) a polyethylene terephthalate film as a drug non-adsorptive layer having a thickness of 0.1 to 10 μm, and

(2) a flexible polymer film, a non-woven fabric, or a woven fabric having a thickness of 1 to 200 μm.

Moreover, the pressure-sensitive adhesive layer containing the female hormone (i.e., the active ingredient) is laminated next to the drug non-adsorptive layer side of the backing.

In Figure 1, symbol A is the backing layer. The backing layer includes flexible film 1 and non-adsorptive layer 2. The pressure-sensitive adhesive layer 3 is laminated on the non-adsorptive layer side (2) of the backing (A) to prevent the active ingredient being adsorbed to the backing. **New independent claims 10 and 11 specifically claim "said pressure-sensitive adhesive layer being adjacent to said drug non-adsorptive layer," demonstrating the orientation of the layers.**

Drawings

The drawings were objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. The examiner maintains that Figure 1 does not describe the layers as claimed in claims 6 and 7 and has requested replacement drawings. Claims 6 and 7 have been canceled in this amendment in favor of new claims 10 and 11. Applicants respectfully maintain that the no new drawings are needed, since the claims as amended and the drawings now correspond in structure.

The backing is in Figure 1 is noted as A. A has two parts -- 1) the flexible film and 2) the drug non-adsorptive layer. See page 10, lines 5-7, and page 17, lines 17 to page 18, line 2 and Figure 1. The flexible film (#1 in Figure 1) can be made from woven fabrics, non-woven fabrics and polymer films as described on page 18, lines. The non-adsorptive layer (#2 in Figure 1) is a polyethylene terephthalate film as presently claimed. #3 in Figure 1 is a pressure sensitive adhesive layer. #4 in Figure 1 is the release liner. Layers 1, 2, and 3 of the laminate are specifically noted in the claims. Layer 4 is not noted in the claims.

Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. The examiner states that "[t]he specification describes the drug non-adsorptive layer made of polyethylene terephthalate film, and the flexible film can include woven or non-woven fabrics or polymer films (pg. 17, line 17 – pg. 18, line 27). However, the specification also discloses the laminate structure comprises a polyethylene terephthalate film and flexible film or a non-woven fabric or a woven fabric) pg. 6, lines 27-29). Therefore, it is unclear from the specification, what the laminated structure is." This description is correct as described above. The polyethylene terephthalate film is the drug non-adsorptive layer 2. The drug adsorptive layer 2 is laminated to the flexible film 1. Together drug adsorptive layer

2 and flexible film 1 make backing A in Figure 1. Flexible film 1 can be made of many materials including a flexible film, a non-woven material or a woven material. The polyethylene terephthalate film is layer 2, **not** flexible film 1. Applicants respectfully suggest that when read in its entirety, the specification clearly explains the nature and constituents of the laminated structure. Applicants further hope that the above discussion has been helpful.

Claim Rejections – 35 USC § 112

Claims 6-9 were rejected under 35 U.S.C. 112. Independent claims 6 and 7 were canceled with the amendment. Please note that the flexible film layer is not limited to any one specific material. As stated on page on page 18, lines 19-25 of the specification:

> On the other hand, the flexible film to be laminated on the drug non-adsorptive layer is **not limited to any specific one** as long as it can follow the irregularities on the skin or body movements. **Examples** of such a flexible film include woven fabrics, non-woven fabrics, and polymer films made of polyethylene, polypropylene, polyurea, polyurethane, polyester, polyvinyl alcohol, polyvinyl chloride, or polymeric elastomers. (Emphasis added.)

Claim Rejections – 35 USC § 103

1. Claims 6 and 9/6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. (US 6,177,098) in view of Akemi et al. (US 5,242,951).

Claim 6 has been canceled but the references will be discussed in order to move the prosecution of this case forward. The invention of Kawaji et al. relates to a plaster for percutaneous absorption which comprises a laminated backing comprising a polyester film/non-woven fabric of vinylon having an elasticity rate of more than 5% and severance rate of more than 0.5 kg/10 mm in which said polyester film has a

thickness of 1.5-6.0μm, and the unit weight of the vinylon non-woven cloth is 3-12 g/m^2.

As the examiner pointed, Kawaji et al. discloses an external plaster comprising a backing and a pressure-sensitive adhesive layer, wherein the backing is a laminate structure comprising a polyethylene terephthalate film and a non-woven fabric.

The purpose of using polyester film (polyethylene terephthalate film) is to prevent the sublimation of active ingredient from the adhesive layer, and to achieve ODT (occlusive dressing technique) effect, and flexibility of the plaster.

On the contrary, in the present invention, a polyethylene terephthalate film is act as drug non-adsorptive layer, and therefore, the purpose of the present invention is clearly different from the invention of Kawaji et al.

Further, the laminate structure of the external patch of Kawaji et al. is as follow:

(Polyester film, i.e. polyethylene terephthalate film/Non-woven fabric of vinylon/Adhesive layer)//skin surface

On the contrary, the laminate structure of the external patch of the present invention is as follow;

(Flexible polymer film/Drug non-adsorptive layer, i.e., polyethylene terephthalate film/Adhesive layer)//skin surface

Therefore, the laminate structure of the present invention is clearly different from that of Kawaji et al. The Kawaji structure is the completely opposite from the structure taught and claimed in the present application. Given the completely opposite orientation of the laminate layers of the backing taught by the Kawaji reference and the laminate layers of present invention, applicants respectfully maintain that an additional discussion of secondary reference, Akemi et al., is not necessary at this time. The Akemi et al. reference was discussed in depth in the May 12, 2008 amendment. The prior arguments are incorporated in this response.

2. Claim 8/6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al. in view of Akemi et al. and further in view of Radloff et al. (WO 2002/038134). US 2004/0091521 will be used herein as an English equivalent translation of WO 2002/038134.

Claim 6 has been canceled, but the Radloff et al. reference will be discussed in order to move the prosecution of this case forward. The Examiner pointed that Radloff et al. discloses a backing having a laminate structure comprising polyethylene terephthalate and a flexible film made of low-density polyethylene.

Further the Examiner pointed that it would have been obvious to one of ordinary skill in the art to modify the materials of the backing of Akemi et al. to be that of Radloff et al. in order to provide the desired effect and elasticity/flexibility.

However, please note that the invention of Radloff et al. is an active substance patch comprising a laminate coated on its skin-facing side with an adhesive which comprises an active substance, the laminate having at least two plies. The side of the patch remote from the skin carries a barrier layer which is impervious to the active substance, its skin-facing side carries a backing layer, and these two layers can be separated from one another.

Therefore, the laminate structure of the present invention is clearly different from that of Radloff et al. as following.

The laminate structure of the patch of Radloff et al. is as follow:

(Barrier layer/Backing layer/Adhesive layer containing active substance)//skin surface

On the contrary, the laminate structure of the external patch of the present invention is as follow:

(Flexible polymer film/Drug non-adsorptive layer, i.e., polyethylene terephthalate film/Adhesive layer)//skin surface.

The Radloff reference does not teach the adhesive layer adjacent to the barrier layer as disclosed and claimed in the present application.

3. Claims 6 and 9/6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Kawaji et al.

4. Claim 8/6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Akemi et al. in view of Kawaji et al. and further in view of Radloff et al.

Claim 6 was canceled with this amendment. The arguments presented above are repeated here. Applicants respectfully request that the new independent claims 10 and 11 be examined.

5. Claims 7 and 9/7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. (Us 5,693,335) in view of Hoffman et al. (US 5,393,529) and further in view of Muraoka et al. (US 5,876,745).

6. Claim 8/7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Xia et al. in view of Hoffman et al. and further in view of Muraoka et al. and further in view of Radloff et al.

Claim 7 was canceled with this amendment. Applicants respectfully request that the new independent claims 10 and 11 be examined.

CONCLUSION

If the Examiner has any questions or suggested Examiner's amendments, the Examiner is respectfully requested to call the undersigned.

The Commissioner is hereby authorized to charge any additional fees, or to credit any overpayment, to Deposit Account No. 50-3195.

Respectfully submitted,

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